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The Hatch-Waxman Act: Proposed Legislative Changes Affecting Pharmaceutical Patents

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Wendy H. Schacht and John R. Thomas
Resources, Science, and Industry Division

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The Hatch-Waxman Act: Proposed Legislative Changes Affecting Pharmaceutical Patents

SUMMARY

Congressional interest in the cost of pharmaceuticals, particularly for the elderly, has focused attention on several areas where the federal government has programs and policies associated with the development and accessibility of drugs in the marketplace. One of the most prominent legislative initiatives in this area is P.L. 98-417, the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act) which made several significant changes to the patent laws as they apply to pharmaceutical products. These changes include provisions for extending the term of a patent to reflect regulatory delays encountered in obtaining marketing approval by the Food and Drug Administration (FDA); a statutory exemption from patent infringement for activities associated with regulatory marketing approval; establishment of mechanisms to challenge the validity of a pharmaceutical patent; and a reward for disputing the validity, enforceability, or infringement of a patented and approved drug. The Hatch-Waxman Act also provides the FDA with certain authorities to offer periods of marketing exclusivity for a pharmaceutical independent of the rights conferred by patents.

The provisions contained in the Act were designed to balance the need for innovative new pharmaceuticals and the availability of less expensive generic drugs. Over the 18 years since passage of the Hatch-Waxman Act, questions have been raised as to whether or not implementation of certain portions of the law has led to unintended consequences that have affected this balance.

Some argue that brand name companies and/or generic firms have exploited provisions of the Act to prevent the timely introduction of lower cost drugs. Other observers assert that no such pattern of abuse is evident and that while a few isolated cases of "misinterpretation" of the law have arisen, these can be addressed through existing procedures. Several bills were introduced in the past several years, as well as in the 108th Congress, that would amend the Hatch-Waxman Act. Title XI of P.L. 108-173 (H.R. 1), the Medicare Prescription Drug and Modernization Act of 2003, as signed into law on December 8, 2003, makes changes to the current law to address issues of pharmaceutical patents listed in the Orange Book maintained by the Food and Drug Administration, patent challenges by generic firms, and the award of market exclusivity, among other things.

MOST RECENT DEVELOPMENTS

P.L. 98-417, the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act), made several significant changes to the patent laws designed to encourage innovation in the pharmaceutical industry while facilitating the speedy introduction of lower-cost generic drugs. However, over the 18 years since passage of the Hatch-Waxman Act, concerns have arisen as to whether or not implementation of certain portions of the law has led to unintended consequences that have affected attainment of the legislation's original goals. Some argue that brand name companies and/or generic firms have exploited provisions of the Act to prevent the timely introduction of lower cost drugs. Other Members of Congress and additional experts maintain that no pattern of abuse exists and that while a few isolated cases of "misinterpretation" of the law have arisen, these can be addressed through existing procedures and legislative changes are not necessary. In the first session of the 108th Congress several bills were introduced that would amend the Hatch-Waxman Act. Title XI of P.L. 108-173 (H.R. 1), the Medicare Prescription Drug and Modernization Act of 2003, signed into law by the President on December 8, 2003, makes changes to the Hatch-Waxman Act related to pharmaceutical patents listed in the Orange Book, patent challenges by generic firms, and the award of market exclusivity, among other things. Additional related bills introduced in the first session of the current Congress included S. 1, S. 1225/ H.R. 2491, S. 54, Title II of S. 7, H.R. 828, Title II of H.R. 1199, and H.R. 1733.

BACKGROUND AND ANALYSIS

P.L. 98-417, the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act), made several significant changes to the patent laws designed to encourage innovation in the pharmaceutical industry while facilitating the speedy introduction of lower-cost generic drugs. These changes include provisions for extending the term of a patent to reflect regulatory delays encountered in obtaining marketing approval by the Food and Drug Administration (FDA); a statutory exemption from patent infringement for activities associated with regulatory marketing approval; establishment of mechanisms to challenge the validity of a pharmaceutical patent; and a reward for disputing the validity, enforceability, or infringement of a patented and approved drug. The Hatch-Waxman Act also provides the FDA with certain authorities to offer periods of marketing exclusivity for a pharmaceutical independent of the rights conferred by patents. (For a detailed discussion of the law and its implementation see CRS Report RL30756, *Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984*, by Wendy H. Schacht and John R. Thomas.)

Many experts agree that the Act has had a significant effect on the availability of generic substitutes for brand name drugs. Generics generally are rapidly available after patent expiration and at lower prices. Concurrently, given the increasing investment in research and development (R&D) and the gains in research intensity of the pharmaceutical industry, it appears that the 1984 Act has not deterred the search for and the development of new drugs.

However, over the 18 years since passage of the Hatch-Waxman Act, concerns have been expressed as to whether or not implementation of certain portions of the law has led to unintended consequences that have affected attainment of the legislation's original goals. Some argue that a pattern of "abuse" has been associated with the provisions of the Act and that changes should be made to prevent such actions. Among the issues raised are actions associated with pharmaceutical patents listed in the Orange Book, patent challenges by generic firms, and the award of market exclusivity.

Others claim that no such pattern exists and that while a few isolated cases of "misinterpretation" of the law have arisen, these can be addressed through existing procedures and legislative changes are not necessary. To support this position, proponents of the current law point out that 94% of the 8,259 generic applications filed with the FDA raised no patent-related issues. Generic challenges to brand name pharmaceuticals have resulted in only 58 court decisions involving 47 patents. In addition, while the Federal Trade Commission (FTC) may be looking at several circumstances, to date 3 cases have resulted in consent agreements between the parties and the government. (For a detailed discussion of the issues raised see CRS Report RL31379, *The "Hatch-Waxman" Act: Selected Patent-Related Issues*, by Wendy H. Schacht and John R. Thomas.)

General Provisions of the Law

The 1984 Hatch-Waxman Act modified the 1952 Patent Act by creating a statutory exemption from certain claims of patent infringement. Generic manufacturers may commence work on a generic version of an approved brand name drug any time during the life of the patent, so long as that work furthers compliance with FDA regulations.

Although the 1984 Act provides a safe harbor from patent infringement, it also requires would-be manufacturers of generic drugs to engage in a specialized certification procedure. The core feature of this process is that a request for FDA marketing approval is treated as an "artificial" act of patent infringement. This feature was intended to allow judicial resolution of the validity, enforceability and infringement of patent rights afforded by the U.S. Patent and Trademark Office (USPTO).

Under PL 98-417, each holder of an approved new drug application (NDA) must list pertinent patents it believes would be infringed if a generic drug were marketed before the expiration of these patents. The FDA maintains this list of patents in its publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book."

A generic firm must certify its intentions with regard to each patent associated with the generic drug it seeks to market. Four possibilities exist under the 1984 Act: (1) that patent information on the drug has not been filed; (2) that the patent has already expired; (3) the date on which the patent will expire; or (4) that the patent is invalid or will not be infringed by the manufacture, use or sale of the drug for which the ANDA is submitted.

These certifications are respectively termed paragraph I, II, III, and IV certifications. An "abbreviated new drug application" (ANDA) certified under paragraphs I or II is approved immediately after meeting all applicable regulatory and scientific requirements.

An ANDA certified under paragraph III must, even after meeting pertinent regulatory and scientific requirements, wait for approval until the drug's listed patent expires.

An ANDA applicant filing a paragraph IV certification must notify the proprietor of the patent. The patent holder may bring a patent infringement suit within 45 days of receiving such notification. If the patent owner timely brings a patent infringement charge against the ANDA applicant, then the FDA must suspend approval of the ANDA until: (1) the date of the court's decision that the listed drug's patent is either invalid or not infringed; (2) the date the listed drug's patent expires, if the court finds the listed drug's patent infringed; or (3) subject to modification by the court, the date that is 30 months from the date the owner of the listed drug's patent received notice of the filing of a Paragraph IV certification.

Once the brand name company indicates an intent to bring a patent infringement suit against the generic company as a result of the paragraph IV filing, the FDA is prohibited from approving the drug in question for 30 months or until such time that the patent is found to be invalid or not infringed. If, prior to the expiration of 30 months, the court holds that the patent is invalid or would not be infringed, then the FDA will approve the ANDA when that decision occurs. Conversely, if the court holds the patent is not invalid and would be infringed by the product proposed in the ANDA prior to the expiration of 30 months, then the FDA will not approve the ANDA until the patent expires.

The first generic applicant to file a paragraph IV certification is awarded a 180-day market exclusivity period by the FDA. The 180-day market exclusivity period ordinarily begins on the earliest of two dates: (1) the day the drug is first commercially marketed; or (2) the day a court decision holds that the patent which is the subject of the certification is invalid or not infringed. The interpretation of a "court decision" includes the decision of a U.S. district court. A successful defense of a patent infringement suit is not necessary to obtain this exclusivity period.

Selected Patent-Related Issues

The Hatch-Waxman Act requires that when a company submits a new drug application to the Food and Drug Administration for approval, patent information associated with that pharmaceutical be listed in the "Orange Book," an FDA publication. This document provides generic manufacturers with an accessible list of approved drugs that are potentially eligible for abbreviated new drug applications. Responsibility for maintaining the integrity of the Orange Book is an issue. The U.S. Patent and Trademark Office issues patents on pharmaceuticals based upon utility, novelty, and non-obviousness. The FDA provides market approval for drugs based on efficacy and safety. In some cases, certain generic pharmaceutical companies have taken the position that a specific listing is inappropriate. They maintain that subsidiary patents have been added to the Orange Book that do not relate to the patented drug's active ingredient but still delay generic competition. However, the patent system has long allowed improvement patents so long as a sufficient inventive advance exists.

The role of the FDA in adjudicating Orange Book listing disagreements is limited. If a generic pharmaceutical company disputes the accuracy of an Orange Book listing, that enterprise must present the grounds for disagreement to the FDA in writing. The FDA will

then request that the NDA holder confirm the propriety of the listing. Unless the NDA holder withdraws or amends the listing, the FDA will not alter the patent information in the Orange Book.

Under the Hatch-Waxman Act, Orange Book listing issues typically are resolved once the patentee files a patent infringement suit against the ANDA applicant. In other words, the 1984 Act expressly allows the patentee to sue the ANDA applicant for patent infringement. No other avenue for resolution of Orange Book listings is provided in the 1984 Act.

The law also created a statutory exemption from certain claims of patent infringement associated with submitting a request to the FDA for marketing approval for a generic version of a patented pharmaceutical. Several incentives are provided to generic firms to challenge the validity of existing patents through a paragraph IV filing including the 180-day market exclusivity period for the first generic company to make, but not necessarily win, the challenge. Implementation of this provision has led to concerns by some in the community. Originally, FDA regulations required that a generic firm filing an ANDA had to be sued for patent infringement and *win* in court in order to receive approval for market exclusivity. However, in response to a court decision in *Mova Pharmaceutical Corp. v. Shalala*, FDA guidelines were changed to eliminate the necessity for a "successful defense" by a generic manufacturer against claims of patent infringement prior to receiving the 180-day market exclusivity.

Critics argue that these provisions encourage the filing of "sham" paragraph IV certifications as generic companies attempt to obtain the first-to-file position and then work out a "settlement" with the brand name firm that delays introduction of a generic version of the drug. Others maintain that settlements do not necessarily interfere with the timely marketing of generic drugs and are less expensive than court cases that typically take longer than 30 months and are extremely costly.

Once a paragraph IV filing has been made and the patent owner declares the intention to sue for patent infringement, the FDA is prohibited from considering the generic product for 30 months or until the patent is found invalid or not infringed. An automatic 30-month injunction differs from typical infringement cases not involving pharmaceuticals. Commonly, the company suing for infringement places a bond to cover their competitor's market losses should the patent be found invalid or not infringed. If the patent owner prevails, the infringer is required to pay for lost income and may be required to pay treble damages if the infringement was willful. The patent owner may also have the offending product taken off the market. However, given the circumstances surrounding pharmaceuticals, it may be unlikely that a drug, once available for sale and in individual medicine cabinets, would be removed. In addition, given the value of certain pharmaceuticals on the market, it may be impossible for the brand name firm to recoup its monetary loses from generic firms with significantly fewer capital resources.

Concerns also have been raised by some critics as to commencement of the 180-day market exclusivity period. The Hatch-Waxman Act triggers the generic exclusivity in one of two ways: either when the generic manufacturer commences commercial marketing of its drug, or when a court decision finds the NDA holder's patent invalid or not infringed. With regard to the latter provision, the FDA interpreted the law as requiring a decision of the United States Court of Appeals for the Federal Circuit to commence the exclusivity period.

According to the FDA, ANDA applicants that prevailed at the district court level might wish to delay marketing their generic drug until the patent infringement litigation was more conclusively resolved on appeal. The FDA thus hoped to eliminate what it perceived to be a difficult choice for generic applicants: either launch a generic drug while the litigation was still pending on appeal, thereby risking infringement liability if the district court's opinion was overturned by the Court of Appeals or wait until the appeal was decided, which almost certainly meant that the 180-day exclusivity period would have elapsed.

However, the United States District Court for the District Court of Columbia held that the FDA's interpretation of the phrase "a decision of the court" was erroneous. According to Judge Roberts, the correct interpretation of that phrase included decisions of a U.S. district court. Judge Roberts further reasoned that nothing prevented the first ANDA applicant from utilizing the 180-day period if it concluded that the risk of reversal by the Court of Appeals was low; that the FDA interpretation prolonged the period at which drug prices remained at inflated levels; and that exclusivity periods were valuable commodities that could be traded to, among other parties, the NDA holder.

Federal Trade Commission Report

According to the Food and Drug Administration, between 1984 (when the Hatch-Waxman Act passed) and the end of 2000, 8,019 ANDAs were filed. No patent-related issues were raised in 7,536 (or 94%) of these abbreviated new drug applications. In a July 2002 report titled, *Generic Drug Entry Prior to Patent Expiration*, the Federal Trade Commission studied those ANDAs filed between January 1, 1992 and December 31, 2000 containing a paragraph IV certification challenging patents associated with the brand name drug. During this time period, 104 NDAs were the subject of paragraph IV certifications.

The FTC found that the patent owner sued the first generic applicant in 75 instances. Of the patent challenges brought to court and decided as of June 1, 2002, the patent was found to be invalid in 11 cases and the patents were found not to be infringed in 14 cases. Twenty suits resulted in a settlement between the brand name company and the generic firm. The analysis by the FTC indicated that the first 30-month stay expired before a district court decision was reached in 22 of the 75 cases that were litigated or are currently in the process of litigation between the brand name firm and the first generic applicant.

In approximately 85% of the cases where the patent owner sued the first ANDA applicant, the brand name company also sued the second generic applicant. To date, 40 drug products were the subject of court cases. In 29 of these suits, the generic applicant won while in 11 others the decision favored the brand name firm.

During the time period studied, in 8 instances additional patents were listed in the Orange Book after an initial ANDA filing. Six of these cases occurred since 1998. Approval by the FDA was delayed an additional 4 to 40 months. Four cases have been resolved in court to date and the patents were found to be either invalid or not infringed.

The FTC report claims that FDA approval of ANDA applications without a paragraph IV certification took an average 25 months, 15 days. The time between a "complaint" and a district court decision on a patent infringement challenge took an average 25 months, 13

days. The time between a "complaint" and an appellate court decision was an average 37 months, 20 days. Most generic companies have waited for at least a district court decision prior to entering the market. Three-quarters of the patent cases resolved to date have favored the generic firm.

Since 1998, 31 generic products have received an 180-day market exclusivity provided by the FDA. Between 1992 and 1998, no 180-day market exclusivity was granted. The FTC found that 14 of the 20 settlements reached between the brand name companies and generic firms had the potential to "park" the first generic applicant's use of market exclusivity and thereby delay entry of additional generic versions of the product.

Utilizing the results of this study, the FTC made the following recommendations (with accompanying rationale) for changes in existing law:

1. Allow only one automatic 30-month stay per drug product per ANDA. Currently, according to the study, it appears that one stay associated with patents filed prior to the initial ANDA does not delay generic entry beyond the time needed for FDA approval of the filing. However, there appear to be problems associated with later-listed patents. The FTC identified questions as to whether or not later-listed patents actually meet the listing requirements to be included in the Orange Book, noting that the only way to challenge these listings is through a patent infringement suit.

2. Enact legislation to require brand name companies and first-to-file generic firms to provide the FTC with copies of certain agreements between the parties. Antitrust scrutiny should be permitted to insure that such agreements do not delay the first generic's use of the 180-day market exclusivity rights.

The FTC study also recommends that: the term "commercial marketing" be clarified to include instances where the first generic firm markets the brand name drug; the meaning of a "court decision" be codified to include any court decision on the same patent being litigated by the first generic filer; and any dismissal of a declaratory judgment action for lack of a case or controversy should be considered a "court decision" necessary to trigger the 180-day market exclusivity period.

FDA Rule Change

On June 12, 2003, the Food and Drug Administration announced new rules associated with the 30-month stay and the requirements for listing patents in the Orange Book. Originally published as a proposal in the October 24, 2002 Federal Register, the new regulations would allow only one 30-month stay in the approval date of each ANDA or 505(b)(2) application. The agency will now prohibit the Orange Book listing of patents for drug packaging, drug metabolites, and intermediate forms of a drug. Process patents are not to be listed, although product-by-process patent information is required when the product claimed is novel. NDA holders are obligated to provide additional patent-related information upon listing in the Orange Book and sign as to the veracity of the information under threat of criminal charges for false statements. These changes are similar to those suggested by the Federal Trade Commission and became effective on August 18, 2003. However, some experts contend that the FDA does not have the authority to alter application of the Hatch-

Waxman Act through the regulatory process without related legislative changes. They predict that the FDA actions will be challenged in court.

Legislative Initiatives: 108th Congress

Some Members of Congress and other experts maintain that the Hatch-Waxman Act continues to successfully balance the need for innovative new pharmaceuticals and the availability of less expensive generic drugs. They note that since passage of the law, the amount of investment by pharmaceutical companies in biomedical research and development has increased while the number of lower cost generic drugs has expanded significantly. Further, those who oppose changes to the Act argue that existing procedures and current law is sufficient to address any "misinterpretation" or "misuse" of the legislation.

However, Title XI of H.R. 1, passed by both the House and Senate and awaiting the President's signature, makes changes to the Hatch-Waxman Act as it relates to patent listing in the Orange Book, the automatic 30-month stay, and the 180-day market exclusivity provisions. This bill, and others introduced in the 108th Congress are discussed below:

P.L. 108-173, Title XI (H.R. 1): Access to Affordable Pharmaceuticals

Title XI of P.L. 108-173 (H.R. 1), the Medicare Prescription Drug and Modernization Act of 2003, as signed into law by the President on December 8, 2003, permits only one automatic 30-month stay on those patents listed in the Orange Book at the time of a paragraph IV ANDA. Modifications to the default 30-month stay are allowed based on district court judgments. The FDA may approve the ANDA on the date of an appeals court decision, the date of a settlement order or consent decree, or when a district court decision is not appealed. The company filing a paragraph IV certification must submit additional information than is necessary under current law and is required to notify the patent owner of a certification within 20 days. The ANDA applicant may not amend the certification to include a drug different from that approved by the FDA, but may amend the application if seeking approval for a different strength of the same drug.

In a situation where a patent holder does not file an infringement suit within 45 days of notification of a paragraph IV ANDA, the ANDA applicant may request a declaratory judgement regarding the validity of the patent. If sued, the generic firm may file a counter claim to require the patent holder make changes to the Orange Book listings. No damages are to be awarded in either case. In a declaratory judgment action, the NDA holder may obtain confidential access to information contained in the ANDA application.

This legislation permits multiple generic firms to qualify for the 180-day market exclusivity if several ANDA applicants file on the same day. This exclusivity could be forfeited in certain situations including failure to market under specific time constraints, withdrawal of the application, amendment of the certification, failure to obtain approval from the FDA, expiration of all patents, or the determination by the FTC or the Assistant Attorney General that an agreement between the brand name and generic firms violates antitrust laws. Subsequent applicants would not be permitted the 180-day exclusivity. The exclusivity

would begin on the date of the first commercial marketing of the generic by the first ANDA applicant(s).

S. 1, Title VII: Greater Access to Affordable Pharmaceuticals Act

As passed by the Senate on June 27, 2003, Title VII of S. 1, the Prescription Drug and Medicare Improvements Act, allows for only one 30-month stay for those patents that were listed at the time of the filing of a paragraph IV ANDA. The ANDA applicant is required to submit a more detailed statement than mandated under existing law when filing a paragraph IV certification and must notify the patent holder and the brand name company (if different) of such a filing within 20 days. The FDA may approve the ANDA on the date of an appeals court decision, the date of a settlement order or consent decree, or when a district court decision is not appealed.

ANDA applicants are authorized to bring a declaratory judgment action against NDA holders who have listed patents in the Orange Book when the generic firm has not been sued for infringement within 45 days of notification. In such a declaratory judgment action, the company filing an ANDA acts as the plaintiff, likely asserting that the listed patents are invalid or not infringed. In addition, the ANDA applicant, if sued for infringement, may file a counter claim to require the patent holder to change or delete information contained in the Orange Book. No damage awards would be permitted in either case if the ANDA applicant prevailed. If the NDA holder does not file all the required information in the Orange Book, the court may decide not to award treble damages if the ANDA applicant is found to have infringed on the patent.

The 180-day market exclusivity period is to begin on the date of the first commercial marketing by the first generic applicant(s). The first ANDA applicant(s) is required to forfeit the 180-day exclusivity under certain circumstances including failure to market within a specified time frame, withdrawal of the application, amendment of the certification, failure to obtain tentative marketing approval from the FDA, a Federal Trade Commission or Attorney General determination that an agreement with a patent holder violates antitrust laws, or the expiration of all patents.

S. 1225: Greater Access to Affordable Pharmaceuticals Act/H.R. 2491

S. 1225, provides only one 30-month stay for patents listed in the Orange Book at least one day prior to the filing of a paragraph IV ANDA. Related patents listed after the filing of an ANDA do not trigger an additional 30-month stay unless that subsequently issued patent is challenged in a separate proceeding. The ANDA applicant would be permitted to request a declaratory judgement from the courts that the patent is unenforceable, invalid, or not infringed if the patent owner fails to bring an infringement suit within 45 days of the filing of a paragraph IV certification. In addition, under this bill, the ANDA applicant may file a counter claim to require the patent holder to change or delete information in the Orange Book if the patent owner files an infringement suit.

The proposed legislation amends the Hatch-Waxman Act to mandate that the 180-day marketing exclusivity period begins on the date of the final decision of a court from which

no appeal can, or has been taken, or the date of a settlement order or consent decree. The first ANDA applicant will be required to forfeit the 180-day exclusivity to subsequent applicants under certain situations including the failure to market, withdrawal of the application, change of certification from a paragraph IV to a paragraph III, failure to obtain tentative FDA approval, failure to challenge the patent, or an FTC determination that an agreement with a patent holder violates antitrust laws. H.R. 2491 contains similar provisions. (To track additional prescription drug provisions that may be included in this legislation see CRS Report RL31966, *Medicare Prescription Drug and Reform Legislation*, by Jennifer O'Sullivan, et al., and CRS Report RL31503, *Importing Prescription Drugs*, by Blanchard Randall IV and Donna U. Vogt.)

S. 54: Greater Access to Affordable Pharmaceuticals Act/S. 7 (Title II): Prescription Drug Benefit and Cost Containment Act

S. 54, as introduced in the current Congress (and passed by the Senate as S. 812 in the 107th Congress) and Title II of S. 7 would make alterations to the Hatch-Waxman Act that distinguish between patents listed in the Orange Book at the time of FDA approval of the NDA and those patents listed at a later date. Brand name companies must file and list all existing patents within 30 days of NDA approval. If a paragraph IV certification is filed by a generic firm and the patent owner signals an intent to sue, an automatic 30-month stay will be granted during which time the FDA is prohibited from approving the ANDA. A transition period is provided that gives NDA holders 30 days to list all patents upon passage of the bill.

Subsequent patents awarded to the NDA holder must be listed in the Orange Book within 30 days. If the patents are not listed in 30 days, the patent owner loses the right to sue for infringement and the patent is no longer enforceable. If the patent holder does not sue for infringement within 45 days, then the right to sue is forfeited. No automatic injunction may be granted for these patents; a court must decide to grant a preliminary injunction by balancing the following four factors: likelihood of success on the merits, irreparable harm, public interest, and the balance of hardships. However, the court is prohibited from considering the ability to pay damages when granting the injunction.

The ANDA applicant may commence a civil action to correct or delete the original patents listed in the Orange Book. No damages can be awarded for patents that are removed from the Orange Book. Listed patents are required to provide more information regarding the type of patent than is currently mandated.

The legislation mandates that the 180-day exclusivity period begin on the date of a final decision of a court from which no appeal can or has been taken, It further identifies situations in which the first generic company to file a paragraph IV ANDA must forfeit the 180-day market exclusivity. The next ANDA applicant may receive the exclusivity period. In filing a paragraph IV certification, the generic company must be specific as to why the patent is considered invalid or not infringed.

H.R. 1199: Medicare Rx Drug Benefit and Discount Act of 2003

Title II of H.R. 1199 (which addresses Medicare prescription issues) permits the 180-day market exclusivity period to begin on the day of a court decision from which no appeal

can or has been taken. The bill establishes conditions under which the first ANDA applicant must forfeit the 180-day exclusivity provided by the Food and Drug Administration. The next company to file an ANDA containing a paragraph IV certification can receive the market exclusivity period if the original firm forfeits its claims.

Provisions contained in the bill would eliminate the 30-month stay and would require the patent owner to obtain an injunction from the courts under general equitable principles (e.g. a strong case that the patent is valid and infringed; the likelihood that the patent owner would suffer irreparable harm, the balance of hardships, and the public interest). In the absence of an injunction, the FDA may approve the generic after 45 days. Further, ANDA applicants are permitted to bring a "declaratory judgment action"against NDA holders who have listed patents in the Orange Book. This action provides an additional mechanism to determine the validity and infringement status of the patent in question.

Under this proposed bill, the FDA is permitted to approve generic drugs with a medical indication that is no longer under patent, even if a patent or marketing exclusivity covers another indication of that same drug. In these instances, the generic company may not provide instructions on how to use the drug for uses proprietary to another. The FDA may require that the generic drug's label provide necessary safety instructions or stipulate because a particular use is exclusive to another, the drug is not labeled for a particular use.

Agreements reached between brand name companies and generic firms regarding the sale of a generic drug that is equivalent to the drug marketed by the patent owner must be submitted to the FDA and the Federal Trade Commission (FTC) for review within 10 days of their completion. Parties that fail to file such agreements can be fined and imprisoned. The FTC may engage in rulemaking to carry out this legislation. The effective date of the provisions of this Part is 90 days afer its enactment.

H.R. 828: Pharmaceutical Fiscal Accountability Act of 2003

Section 3 of H.R. 828 permits subsequent ANDA holders to obtain FDA marketing approval if certain conditions are not met by the original ANDA applicant.

H.R. 1733: (Title IV) Greater Access to Affordable Pharmaceuticals Act of 2003

The provisions of H.R. 1733 are similar to S. 54 with several exceptions. This bill would eliminate completely the 30 month stay even for those patents that were listed in the Orange Book prior to the passage of the legislation. A preliminary injunction would be required to prevent the approval of an ANDA by a generic firm. A brand name company would not loose the right to enforce a patent if it is not listed in the Orange Book within a specified time frame or if the firm does not begin an infringement suit within 45 days as mandated in S. 54. The bill would also permit the use of citizen petitions.

LEGISLATION

P.L. 108-173/H.R. 1

Medicare Prescription Drug and Modernization Act of 2003. Title XI makes changes to the Hatch-Waxman Act. Introduced June 25, 2003; referred to the House Committees on Energy and Commerce and Ways and Means. Passed House on June 27, 2003. Passed Senate in lieu of S. 1 with an amendment July 7, 2003. Conference report filed November 21, 2003. House agreed to conference report on November 22, 2003; Senate agreed to conference report on November 25, 2003. Signed into law by the President on December 8, 2003.

H.R. 828 (McCarthy, C.)

Section 3 makes changes to the Hatch-Waxman Act. Introduced February 13, 2003; referred to the House Committee on Energy and Commerce.

H.R. 1199 (Rangel)

Medicare Rx Drug Benefit and Discount Act of 2003. Title II makes changes to the Hatch-Waxman Act. Introduced March 24, 2003; referred to the House Committee on Energy and Commerce.

H.R. 1733 (Crowley)

Title IV makes changes to the Hatch-Waxman Act. Introduced April 10, 2003; referred to the House Committees on Energy and Commerce, Ways and Means, Veterans' Affairs, and Administration.

S. 1 (Frist)

Prescription Drug and Medicare Improvements Act. Title VII incorporated as an amendment that makes changes to the Hatch-Waxman Act. S. 1 introduced June 11, 2003; referred to the Senate Committee on Finance. Passed Senate, amended, on June 27, 2003. Senate incorporates this measure in H.R. 1 as an amendment and H.R. 1 passed in lieu on July 7, 2003.

S. 7 (Daschle)

Prescription Drug Benefit and Cost Containment Act of 2003. Title II makes changes to the Hatch-Waxman Act. Introduced January 7, 2003; referred to the Senate Committee on Finance.

S. 54 (Schumer/McCain)

Greater Access to Affordable Pharmaceuticals Act of 2003. Makes changes to the Hatch-Waxman Act similar to those proposed in S. 812 as passed by the Senate in the 107th Congress. Introduced January 7, 2003; referred to the Senate Committee on Health, Education, Labor, and Pensions.

S. 1255 (Gregg/Schumer/McCain/Kennedy)/H.R. 2491 (Emerson)

Greater Access to Affordable Pharmaceuticals Act. Makes changes to the Hatch-Waxman Act. S. 1255 introduced June 10, 2003; referred to the Senate Committee on Health, Education, Labor, and Pensions. Ordered reported from Committee on June 11,

2003. H.R. 2491 introduced June 17, 2003; referred to the House Committees on Energy and Commerce and the Judiciary.

FOR ADDITIONAL READING

CRS Report RL30756. *Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984*, by Wendy H. Schacht and John R. Thomas.

CRS Report RL31379. *The "Hatch-Waxman" Act: Selected Patent-Related Issues*, by Wendy H. Schacht and John R. Thomas.

CRS Report RS21129. *Pharmaceutical Patent Term Extensions: A Brief Explanation*, by Wendy H. Schacht and John R. Thomas.

CRS Report RL30913. *Pharmaceutical Research and Development: A Description and Analysis of the Process*, by Richard E. Rowberg.